REMARKS/ARGUMENTS

Claims 1-13, 15-16, and 19-27 are pending in this application. Claims 1-9, 11, 19, 23, and 24 stand rejected, and claims 10, 12, 13, and 20-22 and 16 are objected to. Claims 25-27 stand withdrawn from examination. Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and the remarks that follow.

Independent claim 1 has been amended to clarify that the hydrolytically unstable linkages are present in the backbone of the crosslinked PEG polymers and that these unstable linkages are hydrolyzable under hydrolysis conditions such that the crosslinked polymeric structure is hydrolytically degradable into smaller PEG fragments. Support for this amendment can be found throughout the application including the Abstract and paragraph [0026] of the published application (i.e., U.S. Publication No. 2004/0076602).

I. Allowed Claims and Allowable Subject Matter

Applicant thanks the Office for acknowledging the allowability of claims 15 and 16. The Applicant also thanks the Office for acknowledging the allowable subject matter of claims 10, 12, 13, and 20-22.

The Office has objected to claims 10, 12, 13, and 20-22 as being dependent upon a rejected base claim (i.e., claim 1). The Office, however, indicates that each of these claims would be allowable if written in independent format. As discussed below, Applicant submits that claim 1, as currently amended, is now in condition for allowance. As such, dependent claims 10, 12, 13, and 20-22 are also currently in condition for allowance.

II. Rejection under 35 U.S.C. §112

Claim 11 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite due to the recitation of "glycerol oligomer" in view of the recitation of "PEG polymers in the absence of non-PEG polymers" in independent claim 1. For the sole purpose of expediting prosecution, Applicant has amended claim 11 by deleting the term "glycerol oligomer". Applicant submits that this rejection has been overcome and requests withdrawal thereof.

III. Rejection under 35 U.S.C. §103

Claims 1-9, 19, and 23-24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,648,506 to Desai et al (hereinafter "Desai"). Applicant traverses this rejection.

To establish a *prima facie* case of obviousness, according to a test predominately used by the courts, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim elements. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

With regard to the Supreme Court's decision in *KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007), it is noted that the Court did not dismiss the usefulness the well-established "teaching, suggestion, or motivation" test set forth above, but merely cautioned against its rigid application. The Supreme Court in *KSR* commented that the Federal Circuit "no doubt has applied the test in accord with these principles [set forth in *KSR*] in many cases." *Id.* 82 USPQ2d at 1396. However, the Supreme Court also opined that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. . ." *Id.* 82 USPQ2d at 1395-96. Regardless of the precise test used, the Court, quoting *In re Kahn*, cautioned that " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' " *Id.* 82 USPQ2d at 1396.

Applicant submits that Desai does not teach, suggest, or otherwise render predictable all aspects of the currently claimed invention. For instance, Desai does not teach, suggest, or otherwise render predictable a crosslinked polymeric structure having at least some hydrolytically unstable linkages present in the backbone of the crosslinked PEG polymers that are hydrolyzable under hydrolysis conditions such that the crosslinked polymeric structure is

hydrolytically degradable into smaller PEG fragments. Desai is devoid of any such teaching or suggestion.

Desai is directed to a drug delivery system in which a water-insoluble drug (i.e., taxol) is bound to a water-soluble polymer to provide a means for delivery of inherently insoluble or poorly soluble drugs in aqueous mediums. Desai teaches that suitable water-soluble polymers include PEG compounds that are modified to provide sites for the attachment of taxol. That is, Desai teaches using a PEG derivative that can be hydrolyzed to release taxol in an active form after delivery of the drug-polymer conjugate. Since the number of taxol molecules per carrier molecule is limited, Desai teaches that PEGs with multiple arms or star molecules can be used to increase the number of taxol molecules bound to a single carrier molecule. See column 6, lines 27-33. As such, the number of taxol molecules capable of binding with the carrier molecule is dependent on the number of free hydroxyl groups incorporated into the mult-arm or star PEG.

Accordingly, Desai teaches that taxol can be linked to PEG via hydrolytically unstable ester linkages. These hydrolyzable linking groups are attached to the PEG-based materials to allow for hydrolysis of the drug-polymer conjugate prior to delivery of the drug to separate the drug from the polymeric carrier. Accordingly, upon hydrolysis, the attached drug may be cleaved from the PEG-based carrier. Desai, however, does not teach, suggest, or otherwise render predictable a crosslinked polymeric structure having at least some hydrolytically unstable linkages present in the backbone of the crosslinked PEG polymers that are hydrolyzable under hydrolysis conditions such that the crosslinked polymeric structure is hydrolytically degradable into smaller PEG fragments as currently recited in independent claim 1.

In contrast to the location of the hydrolytically unstable linkages in Desai, the hydrolytically unstable linkages as recited in independent claim 1 are present in the backbone of the crosslinked PEG polymers. Beneficially, the incorporation of hydrolytically unstable linkages in the backbone of the crosslinked PEG polymers as currently recited allows for the release of the drug and also for hydrolytic degradation of the crosslinked polymeric material into smaller PEG fragments. See paragraph [0023]. As currently claimed, that is, the degradation of the crosslinks in the backbone of the crosslinked PEG polymers allows for the breakdown of the polymeric delivery agent into smaller PEG fragments that can be easily cleared from the body.

Applicant submits that this beneficial currently claimed aspect is not taught or suggested by Desai.

Since Desai does not teach, suggest, or otherwise render predictable all aspects of the currently claimed invention, Applicant submits that this obviousness rejection has been overcome. As such, Applicant requests withdrawal of the obviousness rejection.

IV Conclusion

In view of at least the foregoing claim amendments and remarks, Applicant submits that all of the pending claims are in condition for allowance. Applicant respectfully requests that the claims be allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

John E. Johnson III
Registration No. 58,367

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111

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